

III. REMARKS

Preliminary Remarks

Reconsideration and allowance of the present application based on the following remarks are respectfully requested. Claims 1-23 are pending in this application. Claims 6, 10-19 have been withdrawn from consideration as being directed to a non-elected invention. Claims 2-7 and 10-20 have been cancelled without prejudice. Claims 1, 8, 9, and 21 remain at issue.

In paragraph 26 of the official action, the examiner objected to the lack of consistency concerning SEQ ID NO: 3. The applicants have amended the specification at page 22, line 23 to denote that the internal polynucleotide fragment of the *citA* gene is 481 bp in size. Support for this assertion can be found in the sequence listing under SEQ ID NO: 3 and in the specification at page 22, line 24. In view of the foregoing amendment, the applicants respectfully request withdrawal of the objection to the specification.

In paragraphs 27 and 28, the examiner objected to claims 5 and 21 under 37 C.F.R. §1.75 and 37 C.F.R. §1.75(c) respectively. With regard to claim 5, the examiner alleged that claim 5 was a "substantial duplicate" of claim 4. With regard to claim 22, the examiner alleged the claim failed to limit the subject matter of the previous claim from which it depended upon. The applicants have cancelled both claims 5 and 21 without prejudice, thereby rendering the objections to these claims moot.

Amended claim 1 is now directed to an isolated nucleic acid comprising a nucleotide sequence selected from the group consisting of (a) a nucleotide sequence as set forth in SEQ ID NO: 1, (b) a nucleotide sequence encoding a polypeptide as set forth in SEQ ID NO: 2, and (c) a nucleotide sequence complementary to (a) and (b). Support for amended claim 1 can be found throughout the specification, for example, page 8, lines 16-22 and originally filed claims 1(c), 2 and 7.

Amended claim 21 is now directed to an isolated nucleic acid consisting of a fragment of at least 30 consecutive nucleotides of SEQ ID NO: 1 or the fragment of at least 30 consecutive nucleotides of the full complement of SEQ ID NO: 1. Support for amended claim 21 can be found throughout the specification, for example, on page 4, lines 1-7, and page 8, lines 25-28.

New claim 24 is directed to an isolated nucleic acid comprising a nucleic acid sequence that is at least 90% identical to the sequence of the nucleic acid of claim 1 and encodes a polypeptide having sensor kinase activity. Support for new claim 24 can be found throughout the specification, for example, on page 4, lines 1-7, page 5, lines 15-21, page 7, lines 3-5, and page 10, lines 5-10.

New claim 25 is directed to an isolated nucleic acid that encodes a polypeptide having sensor kinase activity and hybridizes to the complement of the nucleic acid molecule of claim 1 under the following stringent conditions of a final wash of 0.5X SSC at 50°C to 68°C. Support for new claim 25 can be found throughout the specification, for example, on page 4, line 1-7, page 8, lines 23-27, page 9, line 15 to page 10, line 13.

New claims 26-28 are directed to the nucleic acids of claims 1, 24 and 25 in vectors and host cells. Support for these new claims can be found throughout the specification and original claims 23 and page 17, lines 28-34.

The applicants do not intend by these or any amendments to abandon subject matter of the claims as originally filed or later presented, and reserve the right to pursue such subject matter in continuing applications.

Patentability Remarks

Rejection Pursuant to 35 U.S.C. §112, first paragraph, written description

In paragraph 23 of the official action, the rejection of claims 1-3 was maintained under 35 U.S.C. §112, first paragraph, for allegedly lacking written description. Specifically, the examiner reasserted the applicants have not fully described a genus that has sequence identity limitations in the absence of functional limitations so that one of skill in the art would be able to predict the other members of the claimed genus. The examiner alleged the applicants' amendment reciting "native to coryneform bacteria" is not adequately described by the specification. The examiner asserted that while the specification adequately describes the genus of polynucleotides within the % identity range in the claims (i.e., at least 90%), the specification does not adequately describe the subgenus of polynucleotides within the % identity range claimed that are native to coryneform. The examiner suggested two things. First, the examiner suggested adding clear functional limitations to the claims wherein the

polynucleotide claimed must encode a polypeptide having sensor kinase activity. Second, the examiner suggested deleting the phrase "native to coryneform bacteria."

Solely for the purpose of expediting prosecution, and without prejudice to the applicants' right to seek broader claims in a continuing application, the applicants have amended claim 1, thereby removing these phrases, and has cancelled claims 2 and 3. Claim 1 is now directed to an isolated nucleic acid molecule comprising a nucleotide sequence selected from the group consisting of (a) a nucleotide sequence as set forth in SEQ ID NO: 1, (b) a nucleotide sequence encoding a polypeptide as set forth in SEQ ID NO: 2, and (c) a nucleotide sequence complementary to (a) and (b).

New claims 24 and 25 are directed to variants of the CitA sensor kinase protein that are at least 90% identical to the nucleotide sequences of claim 1 and that exhibit sensor kinase activity. These structural and functional characteristics of the subject matter of new claims 24 and 25 meet the Written Description Guidelines of the United States Patent Office (February, 2000). In particular, Example 14 of the guidelines teaches that a claimed variant nucleic acid that is substantially similar to a sequence taught in the specification, along with a functional limitation that the claimed variant nucleic acid encode variant polypeptides that exhibit a specified catalytic activity, meets the written description requirement if the required activity can be determined as described in the specification. In the instant case, the claimed variants must each be at least 90% identical to the nucleotide sequences of claim 1 and therefore do not have substantial variation from the sequences taught in the specification. In addition, the claimed variants are limited to those nucleic acids encoding a polypeptide having sensor kinase activity, which the examiner suggested adding as a clear functional limitation to the variant claims. Furthermore, the application discloses more than one example of such polynucleotides, *i.e.*, polynucleotides of SEQ ID NOS: 1 and 2. The specification also teaches the isolation of the *citA* gene from *C. glutamicum* codes for the CitA protein and is a sensor kinase of a two-component system (see page 7, lines 3-5) and the variants of at least 90% must retain this activity (see page 5, lines 15-21). Finally, the stringent hybridization conditions recited in claim 25 are explicitly supported in the specification at page 9, line 35 to page 10, line 10.

Accordingly, based on the Examiner's own recommendations and the teachings of the specification, the structural and functional limitations of new claims 24 and 25 are described in the specification in such a way as to convey to one of skill in the art that the applicants had

possession of the claimed invention at the time of filing the application. In light of the foregoing amendments, the applicants submit that the rejections of claims 1-3 under 35 U.S.C. §112, first paragraph, for lack of written description are moot and should be withdrawn and should not be extended to new claims 24 and 25.

Rejection Pursuant to 35 U.S.C. §112, first paragraph, enablement

In paragraph 24 of the official action, the rejection of claim 8 was maintained under 35 U.S.C. §112, first paragraph, for lacking an enabling deposit. Specifically, the examiner alleged the enabling deposit DSM 13998 did not contain the full address of the depository as required under 37 C.F.R. §§ 1.801-1.809.

The applicants have amended the specification at page 23, line 5 to include the full address of the biological depository.. Accordingly, the applicants submit that this rejection of claim 8 has been overcome and should be withdrawn.

Rejection Pursuant to 35 U.S.C. §112, second paragraph, indefiniteness

In paragraph 29 of the official action, the examiner rejected claims 8 and 9 under 35 U.S.C. §112, second paragraph, for being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. Specifically, the examiner requested clarification as to a claimed fragment of 480 base pairs in claim 8 vs. the disclosure of SEQ ID NO: 3 as a 481 base pair fragment.

Claim 8 is now directed to a vector pCR2.1citAint comprising an internal fragment of the citA gene having a length of 481 bps as set forth in SEQ ID NO: 3, the restriction map of which is reproduced in figure 1, and deposited in the *E. coli* strain Top10/pCR2.1citAint (DSM No. 13998). Claim 9 is now directed to an internal fragment of the citA gene having a length of 481 bp as set forth in SEQ ID NO: 3. In view of the foregoing amendments to claims 8 and 9, and to the specification at page 22, line 24, and SEQ ID NO: 3, the applicants respectfully submit the rejection of claims 8 and 9 under 35 U.S.C. §112, second paragraph, is now moot.

In paragraph 30 of the official action, claim 21 was rejected under 35 U.S.C. §112, second paragraph, as being indefinite. Specifically, the examiner alleged it was unclear if the fragment limitation related to only SEQ ID NO: 1 or also its complement.

Claim 21 has been amended to be directed to an isolated nucleic acid consisting of a fragment of at least 30 consecutive nucleotides of SEQ ID NO: 1 or the fragment of at least 30 consecutive nucleotides of the full complement of SEQ ID NO: 1. It is clear from the amendment, the fragment relates both to being a fragment of SEQ ID NO: 1, and also as being a fragment of the full complement of SEQ ID NO: 1. In view of the foregoing amendment and remarks, the applicants respectfully submits the rejection to claim 21 has been overcome and requests withdrawal of the same.

Rejections Pursuant to 35 U.S.C. §102(e), novelty –

In paragraph 31 of the official action, claims 1-5, 7, and 20-23 were rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Nakagawa *et al.* (U.S. Pat. Appl. Pub. No. (USPAP) US 2002/0197605). Specifically, the examiner asserted Nakagawa *et al.* teach a polynucleotide sequence that is 100% identical to SEQ ID NO: 1 in the instant application as well as fragments, complements, and vectors thereof. The examiner noted the filing of Nakagawa *et al.*, USPAP 2002/0197605 does not pre-date applicants' foreign priority document DE 100 42 740.5 filed August 31, 2000. The examiner suggested filing a translation of said document in order to certify priority back to the August 31, 2000 filing date, and thus remove the rejection.

Submitted herewith is a certified translation of DE 100 42 740.5 on May 14, 2003 (copy of the United States Patent Office stamped receipt enclosed herewith). As noted by the examiner, the present application claims priority to DE 100 42 740.5, filed on August 31, 2000, which is before the filing date of Nakagawa *et al.* (December 18, 2000). As noted by the examiner, the priority to DE 100 42 740.5 is perfected upon submission of the translation. In view of the foregoing, Nakagawa *et al.* are not a proper §102(e) reference. Therefore, the applicants respectfully submits claims 1-5, 7, and 20-23 are not anticipated by Nakagawa *et al.* and request withdrawal of this rejection.

Inventor(s): MÖCKEL *et al.*
Application No.: 09/804,060
Attorney Docket No.: 021123-0279062

IV. CONCLUSION

In view of the foregoing, the claims are now believed to be in form for allowance, and such action is hereby solicited. If any point remains in issue that the examiner feels may be best resolved through a personal or telephone interview, the examiner is **strongly urged** to contact the undersigned at the telephone number indicated below.

Respectfully submitted,
PILLSBURY WINTHROP LLP

By: 

Thomas A. Cawley, Jr., Ph.D.
Registration No.: 40,944
Direct Telephone No.: 703-905-2144

TAC\PAJ
1600 Tysons Boulevard
McLean, VA 22102
Tele. No.: 703-905-2000
Fax No.: 703-905-2500

Enclosure: German Pat. Appl. No. 101 08 463.3 Translation